JUN - 7 2004

K041124

510(k) SUMMARY

Submitted by:	W & H Dentalwerk Buermoos GmbH Ignaz-Glaser-Strasse 53 A - 5111 Buermoos Austria
Contact person:	Ralf Benda Tel.: +43-6274-6236-193 Fax: +43-6274-6236-234
Date of Preparation:	21/04/2004
Device name:	Accessory for: elcoMED SA-200 elcoMED SA-200 C implantMED SI-95
Common name:	Irrigation tubing set and Y-switch
Classification name:	Controller, foot, handpiece and cord
Predicate device:	Irrigation tubings, which were part (accessory) of the submissions of the dental surgical units elcoMED SA-200, elcoMED SA-200 C and implantMED

Device Description:
elcoMED SA-200, elcoMED SA-200 C and implantMED SI-95 consist of a small hand held motor, a foot control and a controller. They are designed for use in dental surgery.
Optimum irrigation of the treatment site is an important factor for successful treatment. The tubing set is used to supply the treatment fluid / coolant from its reservoir via a pump to the motor / handpiece.

Intended use:
- Supply of the fluid from the reservoir via a drip chamber to the pump,
- Passage of the fluid through the pump and
- Supply of the fluid to the handpiece.

Technological Characteristics:
The irrigation tubing set is the update of the previous tubings. It is a single use device and allows an easy and safe replacement prior to use. It is delivered sterile.

Substantial equivalence:
The irrigation tubing sets and the predicate device share the same indication for use and similar characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Mr. Ralf Benda
W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Strasse 53
A- 5111 Buermoos
AUSTRIA

Re: K041124
Trade/Device Name: Irrigation Tubing Set 2.2M and 3.8M
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: April 21, 2004
Received: April 29, 2004

Dear Mr. Benda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041124

Device Name: Irrigation tubing set and y-swich

Indications for Use: The irrigation tubing set is an accessory to dental surgical units.
The irrigation tubing set is used to supply treatment fluid/coolant liquid from the reservoir to the handpiece via a pump

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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